JAN 2 7 2003

K023254
Page 1 of 4

SpeediCath
510(k) SUMMARY
Page 1 of 4

1. **Submitter:**

Coloplast Corp
1940 Commerce Drive
Mankato, MN 56003
USA

Contact Person: Elizabeth Boots

Phone number: 507-386-4362

Fax number: 507-345-3291

Date of Preparation: September 19, 2002

2. **Device name:**

Classification Name: Urological Catheter
Common/usual name: Urinary Catheter for intermittent use
Proprietary Name: Speedicath

3. **Device Classification:**

The SpeediCath Catheter has been classified by the FDA under the heading of Urological Catheters and accessories as a Class II device.

4. **Statement of Substantial Equivalence:**

SpeediCath is substantially equivalent to the following predicate devices:

- EasiCath Set K973070, Coloplast Corp. Branded as the SureCath Set in the US.
- LoFric®Single Use Urinary Catheter K896750, Astra Tech Inc.
- LoFric®Plus Single Use Urinary Catheter K012374, Astra Tech Inc.

5. **Intended Use:**

The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

6. **Device Description:**

The SpeediCath Catheter is a single use, disposable polyurethane catheter. It is coated and placed in a saline solution, packed and sealed in a foil bag and sterilized. The catheter is prelubricated with a coating containing polyvinylpyrrolidone, which binds the water molecules to the surface of the catheter creating a smooth and even lubricating film.

K023254
Page 2 of 4

SpeediCath
510(k) SUMMARY
Page 2 of 4

Substantial equivalence comparison

A comparison matrix for the SpeediCath versus the predicate devices is presented below:

	SpeediCath	**EasiCath Set (identical to the SureCath Set) Coloplast Corp**	**LoFric®Single Use Urinary Catheter, Astra Tech Inc.**	**LoFric®Plus Single Use Urinary Catheter, Astra Tech Inc.**
510 (k) number		K973070	K896750	K012374
Device composition	Polyurethane catheter coated with polyvinylpyrrolidone, placed in a saline solution containing polyvinylpyrrolidone.	Polyvinylchloride catheter coated with polyvinylpyrrolidone, packed with an ampoule with sterile saline solution and sealed in a urine collection bag.	Polyvinylchloride catheter coated with polyvinylpyrrolidone and salt.	Polyether block amide catheter coated with polyvinylpyrrolidone and salt.
Sizes	Female Ch. 6, 8, 10, 12, 14, 16 Male Ch. 8, 10, 12, 14, 16, 18 Tiemann Ch. 10, 12, 14 Pediatric Ch. 6, 8,10 Boy Ch. 6, 8, 10, 12	Female Ch. 8, 10, 12, 14 Male Ch. 8, 10, 12, 14, 16, 18 Pediatric Ch. 6, 8, 10	Female 150mm Ch. 8, 10, 12, 14 Female 200mm Ch. 8, 10, 12, 14, 16, 18 Male Ch. 8, 10, 12, 14, 16, 18, 20, 22, 24 Tiemann Ch. 10, 12, 14, 16, 18 Pediatric 200mm Ch. 6, 8, 10 Boy Ch. 6, 8, 10 (Sizes currently on the market in the US)	Information not available

K023254
Page 3 of 4

SpeediCath
510(k) SUMMARY
Page 3 of 4

	SpeediCath	EasiCath Set (identical to the SureCath Set) Coloplast Corp	LoFric®Single Use Urinary Catheter, Astra Tech Inc.	LoFric®Plus Single Use Urinary Catheter, Astra Tech Inc.
Function of the device	Inserted into the urethra till catheter reaches bladder and allows urine to drain.	Inserted into the urethra till catheter reaches bladder and allows urine to drain into urine collection bag.	Inserted into the urethra till catheter reaches bladder and allows urine to drain.	Inserted into the urethra till catheter reaches bladder and allows urine to drain.
Indication for use	Chronic urine retention. Post-void residual volume (PVR). Voiding dysfunctions.	Chronic urine retention. Voiding dysfunctions.	Intended use is substantially equivalent to LoFric® Plus Single Use Urinary Catheter (according to K012374 Summary).	Intermittent catherization of the urethra.
Features of the device	Hydrophilic coated. Low friction between catheter and urethral mucosa. Ready to use.	Hydrophilic coated. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between catheter and urethral mucosa.	Hydrophilic coated. Low friction between the catheter and urethral mucosa.
Sterility	Sterile	Sterile	Sterile	Sterile
Packaging	Peel Pack	Peel Pack	Peel Pack	Peel Pack

K023254
Page 4 of 4

SpeediCath
510(k) SUMMARY
Page 4 of 4

7. Summary of Safety Testing:
A summary of the safety testing performed on the coated catheter is listed below.

Test	Reference	Results
Intracutaneous Test in the Rabbit	Scantox, DK Lab no.46511	"Negligible" according to ISO 10993, Part 10, Section 5.4.
Systemic Injection Test in the Mouse	Scantox, DK Lab no.46512	No clinical signs of toxicity, meeting the requirements of USP 24 (2000).
Vaginal Irritation Test – ISO Method	Sterilization Technical Services, USA Test no. T02-1551	Meets the requirements of Vaginal Irritation Test ISO Method (ISO 10993-10:1995).
Test for Delayed Contact Hypersensitivity Using the Guinea Pig Maximization Test	Scantox, DK Lab no. 46510	No evidence of delayed contact hypersensitivity according to ISO 10993, Part 10.
In Vitro Cytotoxicity Assay (Elusion test)	Scantox, DK 46508	Passed the requirements of USP 24 (cytotoxicity grade ≤2).
Agar overlay (Cytotoxicity Assay)	Nelson Laboratories, US Lab no. 215085	Meets requirements of USP 25 (cytotoxicity grade ≤2)
Ames test	Scantox, DK Lab no. 48826	Not mutagenic (OECD guideline no. 471 (1997) and ICH Tripartite Harmonised Guidelines (1995 and 1997))

Conclusion: Passed all tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2003

Ms. Elizabeth Boots
Vice President Quality Assurance
Coloplast Corp.
1940 Commerce Drive
NORTH MANKATO, MN 56003

Re: K023254
Trade/Device Name: SpeediCath
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological catheter and accessories
Regulatory Class: II
Product Code: 78 GBM
Dated: January 15, 2003
Received: January 16, 2003

Dear Ms. Boots:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K023254
Page 1 of 1

510(k) Number (if known): K023254

Device Name: SpeediCath

Indications for Use:

The SpeediCath catheter is indicated for use by patients with chronic urine retention and patients with a post void residual volume (PVR) due to neurogenic and non-neurogenic voiding dysfunction. The catheter is inserted into the urethra to reach the bladder allowing urine to drain.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Ragsdale

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023254